754(M) PORTABLE VENTILATOR

TEST

PROCEDURES

Revision Record

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754(M) TEST PROCEDURE

1 GENERAL:

1.1 GENERAL SETTINGS

1.1.1 All tests performed with calibrated in house test equipment.

Burn In unit using these minimal settings

1.1.1.1 Mode = A/C
1.1.1.2 Rate = 15 BPM
1.1.1.3 I time = 1.5 second
1.1.1.1 Vt = 750 ml
1.1.1.2 FIO2 = 21%
1.1.1.3 External Air = OFF
1.1.1.4 Sigh = OFF
1.1.1.5 Peep = 0 cmH2O
1.1.1.6 Pressure Plateau = OFF
1.1.1.7 High Pressure Alarm = 100 cmH2O
1.1.1.8 Low Pressure Alarm = 0 cmH2O.

1.1.2 Note: Under certain conditions it is permitted to use 30 BPM, 1.0 I time and Vt of 950ml to exercise the unit more vigorously for periods not to exceed 8 hours unattended.

1.2 CONNECTIONS

1.2.1 Connect oxygen and external air to 754, pressurize to 50 PSI.

1.2.2 Connect disposable ventilator circuit to its respective gas outlet, transducer, and exhalation valve connectors.

1.2.3 Connect AC Power Supply between External Power Jack and external power source.

1.2.4 Connect battery pack.

1.3 SETTINGS

1.3.1 Unless otherwise stated, use the following settings

1.3.1.1 Mode = A/C
1.3.1.2 Rate = 15 BPM
1.3.1.3 I time = 1.0 second
1.3.1.4 Vt = 750 ml
1.3.1.5 FIO2 = 21%
1.3.1.6 External Air = ON
1.3.1.7 Sigh = OFF
1.3.1.8 Peep = 0 cmH2O
1.3.1.9 Pressure Plateau = OFF

1.3.1.10 High Pressure Alarm = 100 cmH2O

1.3.1.11 Low Pressure Alarm = 0 cmH2O.

Note: When going from one setting to another, a learning breath occurs as the unit's internal controls adjust. A Vt Alarm may occur during the learning breath, it deactivates on the next breath. This is acceptable.

1.4 RT-200/Model 100

1.4.1 When referring to the RT-200, the number in parenthesis given after the reference is the operating mode the RT-200 should be in for that test (Example: RT-200 (41) is the volume reading for oxygen).

1.4.2 When referring to the Model 100 (M100), the information given in parenthesis is the connection point, then, any change in measurement parameters in the M100s menu structure. (Example: "M100: High Flow: Gas Type: O_2" will set the High Flow Input for Oxygen compensation). When using the Model 100, always use the gain setting that will give the best resolution reading. Ex.: Use a gain of 4 (max 50 LPM) when testing flows of 40 LPM. Set Sweep time For 16 seconds (SW 16s) and measurements for Continuous readings (Meas. Cont.). Unless otherwise stated, use Gas Type: Air.

1.4.3 A Disconnect Alarm may occur while using the RT-200/M100 (especially during low gas flows). This happens because the RT-200/M100 flow sensor's negligible backpressure produces no pressure rise sensed by the ventilator's airway transducer. This is acceptable.

1.5 TEST LUNG

1.5.1 When using test lung, unless otherwise stated, use settings:

1.5.1.1 R = 5

1.5.1.2 Compliance = .050 L/cmH2O.

2 TIDAL VOLUME

2.1 OXYGEN

2.1.1 Set Air/Oxygen mixer control to 100%.

2.1.2 Connect disposable ventilator circuit to RT-200 (41)/M100: High Flow: Gas Type: O2.

2.1.3 Test the tidal volumes from 200 - 3000 ml using the settings given in Table 1. Work from smallest to highest values:

TABLE 1

Vt Set	I Time	Rate
200 ml	0.4 Sec	50bpm

300 ml	1.2 Sec	17bpm
500 ml	0.5 Sec	40bpm
500 ml	0.6 Sec	33bpm
500 ml	1.0 Sec	20bpm
500 ml	1.5 Sec	13bpm
500 ml	2.0 Sec	10bpm
750 ml	1.0 Sec	20bpm
1600 ml	2.4 Sec	12bpm
3000 ml	3.0 Sec	6bpm

2.1.4 When going from one setting to another, allow a learning breath to occur before taking measurements.

2.1.5 Tidal volume readings from RT-200/M100 must be within +/- 10% of Vt setting.

2.2 EXTERNAL AIR

2.2.1 Set Air/Oxygen Mixer to 21%. Set external air to "ON".

2.2.2 Connect disposable ventilator circuit to RT-200 (42)/M100: High Flow: Gas Type: Air.

2.2.3 Test the tidal volumes from 200 - 3000 ml using the settings given in 2.1.3. Work from smallest to highest values.

2.2.4 When going from one setting to another, allow a learning breath to occur before taking measurements.

2.2.5 Tidal volume readings from RT-200/M100 must be within +/- 10% of Vt setting.

2.3 COMPRESSOR

2.3.1 Set Air/Oxygen Mixer to 21%. Set external air to "OFF".

2.3.2 Connect disposable ventilator circuit to adult test lung.

2.3.3 Use a resistance of 5 and a compliance of .050 L/cmH2O.

2.3.4 Use one lung for tidal volumes from 200 - 2000 ml. Use dual lungs for 3000 ml setting.

2.3.5 Test the tidal volumes from 200 - 3000 ml using the settings given in Table One. Work from smallest to highest values.

2.3.6 When going from one setting to another, allow a learning breath to occur before taking measurements.

2.3.7 Tidal volume readings from test lung must be within +/- 10% of Vt setting.

3 FIO2

Note: The Oxygen Analyzer must be calibrated on a daily basis before initial use.

3.1 EXTERNAL AIR & O2

3.1.1 Setup

3.1.1.1 Set Air/Oxygen mixer control to 21%.

3.1.1.2 Set External Air to "On".

3.1.1.3 Connect disposable ventilator circuit to adult test lung.

3.1.1.3.1 Use a resistance of 5 and a compliance of .050 L/cmH2O.

3.1.1.4 Set I time to 1.0 sec and Vt to 500 ml.

3.1.1.5 Connect oxygen sensor to 22 mm gas outlet. Connect 22 mm disposable hose to oxygen sensor.

3.1.2 Measure oxygen concentrations

3.1.2.1 Take oxygen concentration measurements at 21%, 40%, 60%, and 100%.

3.1.2.2 When making setting adjustments, allow a few breaths for the readings to settle.

3.1.2.3 Readings must be within +/- 10% of FIO2 settings.

3.2 COMPRESSOR & O2

3.2.1 Setup

3.2.1.1 Set Air/Oxygen mixer control to 21%.

3.2.1.2 Set External Air to "Off".

3.2.1.3 Connect disposable ventilator circuit to adult test lung.

3.2.1.3.1 Use a resistance of 5 and a compliance of .050 L/cmH2O.

3.2.1.4 Set I time to 1.0 sec and Vt to 500 ml.

3.2.1.5 Connect oxygen sensor to 22 mm gas outlet. Connect 22 mm disposable hose to oxygen sensor.

3.2.2 Measure oxygen concentrations

3.2.2.1 Take oxygen concentration measurements at 21%, 40%, 60%, and 100%.

3.2.2.2 When making setting adjustments, allow a few breaths for the readings to settle.

3.2.2.3 Readings must be within +/- 10% of FIO2 settings.

3.2.2.4 Readings may fluctuate more with compressor than with external air.

4 PEEP

4.1 SETUP

4.1.1 The default value for peep is 0 cmH2O.

4.1.2 Connect disposable ventilator circuit to test lung.

4.1.3 Use a resistance of 5 and a compliance of .050 L/cmH2O.

4.1.4 Use following unit settings

4.1.4.1 Mode = A/C
4.1.4.2 Rate = 15 BPM;
4.1.4.3 I = 1.0 SEC;
4.1.4.4 Vt = 500 ml.
4.1.4.5 FI02 = 21%; External Air = "OFF".

4.2 CONTROL

4.2.1 Press the peep push-button once.
4.2.2 An audible beep should occur.
4.2.3 The peep LCD indicator should increase by 1 cmH2O.
4.2.4 Repeatedly press Peep push-button. Each time the push-button is pressed:
4.2.4.1 An audible beep should be heard.
4.2.4.2 The peep LCD indicator should increase by 1 cmH2O.
4.2.5 After reaching a value of 20 cmH2O, press the button once.
4.2.5.1 An audible beep should be heard.
4.2.5.2 The LCD indicator should read 0 cmH2O.
4.2.6 Press and hold the peep button.
4.2.6.1 One audible beep is heard.
4.2.6.2 The LCD indicator should begin to scroll up in value as long as the peep button is held.
4.2.6.3 After reaching 20 cmH2O, the peep value should scroll back to 0 cmH2O.

4.3 PEEP LEAK

4.3.1 Using 1/8 hosebarb tee, 1/8 ID tubing, and a 3/16 hosebarb x 1/8 hosebarb adapter, connect transducer line to RT-200 (12)/M100: Low Pressure +.
4.3.2 Set peep value to 4 cmH2O.
4.3.2.1 Unit will "learn" the peep value. Allow a minute or so for the unit to learn peep. You may need to lower the rate to 10 BPM to decrease learning time. During the learning phase, there may be some autotriggering. This is acceptable.
4.3.2.2 When the unit has reached 4.0 cmH2O (+/- 1.5 cmH2O), record the value.
4.3.2.3 Turn rate to 1 BPM.
4.3.2.3.1 In 18 seconds after the last breath (19 sec - I time), an Apnea alarm should occur.
4.3.2.3.2 If an Assisted breath occurs before the Apnea alarm, the unit fails Peep Leak test.
4.3.2.3.3 Peep should cancel during Apnea alarm.
4.3.2.4 Cancel Apnea alarm. Peep should reset itself to pre-apnea setting.
4.3.3 Set Peep value to 20 cmH2O and Rate to 15 BPM.

4.3.3.1 Unit will "learn" the peep value. Allow a minute or so for the unit to learn peep. You may need to lower the rate to 10 BPM to decrease learning time. During the learning phase, there may be some autotriggering. This is acceptable.

4.3.3.2 When the unit has reached 20.0 cmH2O (+/- 1.5 cmH2O), record the value.

4.3.3.3 Turn rate to 1 BPM.

4.3.3.3.1 In 18 seconds after the last breath (19 sec - I time), an Apnea alarm should occur.

4.3.3.3.2 If an Assisted breath occurs before the Apnea alarm, the unit fails Peep Leak test.

4.3.3.3.3 Peep should cancel during Apnea alarm.

4.3.3.4 Cancel Apnea alarm. Peep should reset itself to pre-apnea setting.

4.4 COUGH PROTECTION

4.4.1 Allow a minute or so for the unit to learn peep of 20 cmH2O.

4.4.2 Once peep is learned, during expiratory pause, push down on lung. This is simulating a patient cough.

4.4.2.1 The exhalation valve should open up.

4.4.2.2 Airway pressure should start to go down to 0 cmH2O.

4.4.2.3 An Assisted breath will be triggered when the airway pressure drops below baseline.

4.5 HIGH PEEP ALARM

4.5.1 Setup

4.5.1.1 Set Rate = 100 BPM.

4.5.1.2 I time = .2 Sec.

4.5.1.3 Vt = 180 ml.

4.5.1.4 FIO2 = 21%.

4.5.1.5 Peep = 4 cmH2O.

4.5.1.6 External Air = "OFF.

4.5.2 Slowly increase rate until unit begins to autopeep. When the autopeep value goes higher than 4 cmH2O, the High Peep alarm will activate.

5 APNEA:

5.1 SETUP

5.1.1 Set External Air = "ON".

5.1.2 Connect disposable ventilator circuit to test lung.

5.1.2.1 Use a resistance of 5 and a compliance of .015 L/cmH2O.

5.2 APNEA IN A/C & SIMV

5.2.1 Use settings

5.2.1.1 Mode = A/C.

5.2.1.2 Rate = 15 BPM.

5.2.1.3 I time = 1.0 Sec.

5.2.1.4 Vt = 500 ml.

5.2.1.5 FIO2 = 21%.

5.2.1.6 Peep = 0 cmH2O.

5.2.2 Reduce rate to 1 BPM.

5.2.2.1 Apnea alarm should trigger in 18 Sec (19 Sec - I time) after last breath.

5.2.2.2 Put hose circuit on RT-200 (45)/M100: High Flow: Trigger: ON and measure the rate. It should be 12 BPM (+/- 10%).

5.2.2.3 Using RT-200/M100, measure I time (RT-200(46)) and Vt (RT-200(42)). They should both be at the current unit settings (+/- 10%).

5.2.3 Press the Mute/Cancel button and cancel Apnea. Settings should go back to pre-apnea conditions.

5.3 APNEA IN CPAP

5.3.1 Connect disposable ventilator circuit to test lung.

5.3.2 Use a resistance of 5 and a compliance of .015 L/cmH2O

5.3.3 Use Settings

5.3.3.1 Mode = CPAP.

5.3.3.2 FIO2 = 21%.

5.3.3.3 Peep = 0 cmH2O.

5.3.4 Generate an assisted breath by pulling up on test lung.

5.3.4.1 The Apnea-CPAP alarm should occur 10 seconds after the assisted breath.

5.3.4.2 The unit should have a PIP relief of 40 cmH2O (+/- 10%). Use the gauge on the test lung to measure this value.

5.3.4.3 Connect the hose circuit to the RT-200/M100

5.3.4.4 Using RT-200 (#45)/M100, measure the Rate. It should be 12 BPM (+/- 10%).

5.3.4.5 Using RT-200 (#46)/M100, measure the I time. It should be 1.667 Sec (+/- 10%).

5.3.4.6 Using RT-200 (#36)/M100: Gas Type: Air, measure the flow. It should be 30 LPM (+/-10%).

5.3.5 Press the Mute/Cancel button and cancel Apnea. Settings should go back to pre-apnea conditions.

6 OPERATIONAL

6.1 EXTERNAL POWER

6.1.1 Connect AC Power Supply between External Power Jack and external power source.

6.1.2 Disconnect battery.

6.1.3 Verify unit operates while using external power.

6.2 BATTERY

6.2.1 Connect battery.

6.2.2 Disconnect external power.

6.2.2.1 An External Power Fail alarm should occur. Check off this alarm in the Alarms section.

6.2.2.2 Cancel alarm by pushing Mute/Cancel button.

6.2.2.3 Power Information Center should read Battery icon "OK".

6.2.3 Verify unit operates while using battery power.

6.2.4 Reconnect External Power Supply and measure charging current going into battery.

6.3 POWER UP DEFAULTS

6.3.1 With external air connected and pressurized.

6.3.1.1 Set External Air button to "OFF".

6.3.1.2 Set Peep = 4 cmH2O.

6.3.1.3 Set Sigh = “ON”.

6.3.2 Turn off unit. Turn unit back on.

6.3.2.1 External Air LCD should read "ON"

6.3.2.2 Peep = 0 cmH2O

6.3.2.3 Sigh = Off.

6.3.3 Pressure Plateau also defaults to the Off position when the unit is first turned on. Sigh defaults to "OFF" when Pressure Plateau is turned on.

6.4 A/C MODE

6.4.1 Control Breath

6.4.1.1 Verify in the Assist/Control mode that unit gives control breaths at the given settings.

6.4.1.2 Use the following settings to verify the disposable ventilator circuit mushroom inflates and deflates properly and that there is no retard of patient exhalation. The airway pressure must reach 0 cmH2O before the start of the next breath.

6.4.1.2.1 Resistance = 20
6.4.1.2.2 Compliance = .050 L/cmH2O
6.4.1.2.3 Rate = 20 BPM
6.4.1.2.4 I time = 1.0 sec.
6.4.1.2.5 Vt = 500 ml
6.4.1.2.6 Using compressor.

6.4.2 Assisted Breath
6.4.2.1 Put rate to 8 BPM.
6.4.2.2 Connect hose circuit to test lung.
6.4.2.3 During expiratory pause, pull up on lung to generate a negative pressure. When a negative pressure is sensed, an assisted breath should be given at the current settings.

6.5 SIMV

6.5.1 Control Breath
6.5.1.1 Verify in the SIMV mode that unit gives control breaths at the given settings.

6.5.2 Assisted Breath
6.5.2.1 Put rate to 8 BPM and connect hose circuit to test lung.
6.5.2.2 During expiratory pause, pull up on lung to generate a negative pressure.
6.5.2.3 When a negative pressure is sensed in the "time window",
6.5.2.3.1 An Assisted breath is generated
6.5.2.3.2 The inspiratory cycle is synchronized with the patient's ventilatory effort.

6.5.3 Demand Breath
6.5.3.1 Put rate to 8 BPM.
6.5.3.2 Connect hose circuit to test lung.
6.5.3.3 During expiratory pause, pull up on lung to generate a negative pressure. When a negative pressure is sensed outside the "time window":
6.5.3.3.1 A Demand breath is generated
6.5.3.3.2 The inspiratory cycle is not affected by this breath.
6.5.3.4 The flow of a Demand breath has a default value of 60 LPM. Connect hose circuit to RT-200 (36)/M100: High Flow: Gas Type: Air. Use 21% external air. Disconnect green transducer line from patient valve. Cover up fitting hole and generate a negative pressure by gently pulling in on green transducer hose using a syringe. Either a demand breath or an assisted breath will be generated. The flow of the demand breath should be 60 LPM (+/- 10%).

6.6 CPAP

6.6.1 Spontaneous Flow

6.6.1.1 Put unit in CPAP mode.

6.6.1.2 Generate a spontaneous flow as described in 6.5.3.4. Flow should be 60 LPM (+/- 10%).

6.6.2 Demand

6.6.2.1 Reconnect green transducer line to patient valve. Connect hose circuit to test lung.

6.6.2.2 Generate a demand breath by pulling up on test lung. The demand breath should last as long as there is a negative pressure being generated. Verify by varying duration and strength of negative pressure generation.

7 CONTROLS / ALARMS / LCD INDICATORS

Note: For each of the following controls, make sure the push-buttons and knobs operate smoothly. For push-buttons, make sure they do not hang up. For knobs, check that they are aligned, tight, and have full range of motion. When checking controls, verify associated alarms operate per operators manual. Verify the control's LCD setpoints read the proper values.

7.1 EXTERNAL AIR

7.1.1 Push-button Control

7.1.1.1 With external air connected (FIO2 = 21%), turn on unit. External Air LCD should read "ON".

7.1.1.2 Press the External Air push-button control

7.1.1.2.1 LCD set point should toggle to "OFF".

7.1.1.2.2 Unit should switch to compressor operation.

7.1.1.3 Press push-button again.

7.1.1.3.1 LCD set point should toggle back to "ON"

7.1.1.3.2 Unit should resume external air operation.

7.1.2 External Air Low/Fail Alarm

7.1.2.1 Lower the external air pressure to 35 PSI (+/- 2 PSI)

7.1.2.1.1 The External Air Low/Fail alarm should activate

7.1.2.1.2 Unit should switch to compressor mode.

7.1.2.2 Restore external air pressure to 45 PSI (+/- 2 PSI)

7.1.2.2.1 Alarm should deactivate.

7.1.2.2.2 Unit should switch to external air mode.

7.2 SIGH

7.2.1 Push Button Control

7.2.1.1 Press the Sigh push-button control.

7.2.1.1.1 LCD should switch to "ON".
7.2.1.1.2 Verify that the first breath after the push-button control is turned on is a sigh breath. A sigh breath's I time and tidal volume are 150% of set values.
7.2.1.1.3 The next breath after the sigh breath should be a normal breath.
7.2.1.2 Press the Sigh push-button control again.
7.2.1.2.1 LCD should switch to "OFF".
7.2.1.3 Sigh is disabled when Pressure Plateau is turned on. It is also disabled in CPAP mode.

7.3 PRESSURE PLATEAU

7.3.1 Setup
7.3.1.1 Connect hose circuit to test lung.
7.3.1.1.1 Use a resistance of 5 and compliance of .050 L/cmH2O.
7.3.1.2 Use settings
7.3.1.2.1 Rate = 15 BPM.
7.3.1.2.2 I time = 1.0 Sec.
7.3.1.2.3 Vt = 750 ml.

7.3.2 Push-button-Control
7.3.2.1 Press the Pressure Plateau push-button control. The LCD setpoint should toggle from "OFF" to the high pressure alarm setting minus 10 cmH2O.
7.3.2.2 Turn the high pressure alarm control to 100 cmH2O. Verify that the Pressure Plateau LCD setpoint reads 90.

7.3.3 Plateau Volume Alarm
7.3.3.1 Turn the high pressure alarm control to 20 cmH2O.
7.3.3.1.1 The Pressure Plateau LCD setpoint should read 10.
7.3.3.1.2 Plateau Volume Alarm should activate.
7.3.3.1.3 The tidal volume being delivered to the test lung should be limited to Pressure Plateau pressure setting.
7.3.3.2 Press the Mute/Cancel push-button control.
7.3.3.2.1 The audible buzzer should deactivate.
7.3.3.2.2 The alarm LED should deactivate.
7.3.3.2.3 The AMC should still display the Plateau Volume Alarm.
7.3.3.3 Turn the High Pressure Alarm LCD setpoint to 30 cmH2O.
7.3.3.3.1 Pressure Plateau LCD should read 20.
7.3.3.3.2 Plateau Volume Alarm should deactivate.

7.4 HIGH PRESSURE ALARM

7.4.1 Setup
7.4.1.1 Connect hose circuit to test lung.

7.4.1.1.1 Use a resistance of 5 and a compliance of .050 L/cmH2O.

7.4.1.2 Use settings

7.4.1.2.1 Rate = 15 BPM.

7.4.1.2.2 I time = 1.0 sec.

7.4.1.2.3 Vt = 850 ml.

7.4.2 High Pressure Alarm

7.4.2.1 Turn the High Pressure Alarm control to 100 cmH2O. Verify the corresponding High Pressure bar graph tic goes to 100 cmH2O.

7.4.2.2 Turn the High Pressure control to 50 cmH2O; High Pressure bar graph tic should move to 50 cmH2O.

7.4.2.3 Turn High Pressure control to 15 cmH2O;

7.4.2.3.1 High Pressure bar graph tic should move to 15 cmH2O.

7.4.2.3.2 The tidal volume being delivered to the test lung should be limited to the High Pressure Alarm pressure setting.

7.4.2.3.3 After four consecutive breaths where the High Pressure setting is reached, the High Pressure Alarm should activate.

7.4.2.4 Turn the High Pressure control to 30 cmH2O.

7.4.2.4.1 High Pressure bar graph tic should move to 30 cmH2O.

7.4.2.4.2 After four consecutive breaths where the High Pressure setting is not reached, the High Pressure Alarm should deactivate.

7.4.3 Pressure Alarm Settings Alarm

7.4.3.1 Turn the Low Pressure control to 40 cmH2O.and the High Pressure control to 30 cmH2O. The Pressure Alarm Settings Alarm should activate.

7.4.3.2 Turn Low Pressure control to 0 cmH2O and the High Pressure Alarm to 100 cmH2O. Pressure Alarm Settings Alarm should deactivate.

7.5 LOW PRESSURE ALARM

7.5.1 Setup

7.5.1.1 Connect hose circuit to test lung.

7.5.1.1.1 Use a resistance of 5 and a compliance of .050 L/cmH2O.

7.5.1.2 Use settings

7.5.1.2.1 Rate = 15 BPM.

7.5.1.2.2 I time = 1.0 sec.

7.5.1.2.3 Vt = 850 ml.

7.5.2 Low Pressure Alarm

7.5.2.1 Turn the Low Pressure Alarm control to 10 cmH2O. Verify the corresponding Low Pressure bar graph tic goes to 10 cmH2O.

7.5.2.2 Turn the Low Pressure control to 50 cmH2O;

7.5.2.2.1 Low Pressure bar graph tic should move to 50 cmH2O.
7.5.2.2.2 After two consecutive breaths where the peak airway pressure does not reach the Low Pressure setting, the Low Pressure Alarm should activate.
7.5.2.3 Turn the Low Pressure setting to 10 cmH2O.
7.5.2.3.1 Low Pressure bar graph tic should move to 10 cmH2O.
7.5.2.3.2 After two consecutive breaths where the peak airway pressure is at or greater than the Low Pressure setting, the alarm should deactivate.

7.6 RATE

7.6.1 Setup
7.6.1.1 Use RT-200 (45)/M100: High Flow and External Air: ON.
7.6.2 Turn Rate control to 15 BPM.
7.6.2.1 Set I time = 1.0 sec. and Vt = 500 ml.
7.6.2.2 Verify Rate measures 15 BPM (+/- 10%).
7.6.3 Turn Rate control to 60 BPM.
7.6.3.1 Set I time = 0.5 sec and Vt = 500 ml.
7.6.3.2 Verify Rate measures 60 BPM (+/- 10%).
7.6.4 Turn Rate control to 150 BPM.
7.6.4.1 Set I time = 0.2 sec and Vt = 200 ml.
7.6.4.2 Verify Rate measures 150 BPM (+/- 10%).

7.7 I TIME

7.7.1 Setup
7.7.1.1 Use RT-200 (46)/ M100: High Flow and External Air: ON.
7.7.1.2 Set Vt = 500 ml.
7.7.2 Turn Inspiration Time control to 0.5 sec.
7.7.2.1 Set Rate = 15 BPM.
7.7.2.2 Verify I time measures 0.5 Sec (+/- 10%).
7.7.3 Turn I time control to 2.0 sec.
7.7.3.1 Set Rate = 15 BPM.
7.7.3.2 Verify I time measures 2.0 Sec (+/- 10%).
7.7.4 Turn I time control to 3.0 sec.
7.7.4.1 Set Rate = 10 BPM.
7.7.4.2 Verify I time measures 3.0 Sec (+/- 10%).
7.7.5 Default 1:2 I:E Ratio
7.7.5.1 Turn Inspiration Time control fully counter clockwise.
7.7.5.2 Verify 1:2 default I:E ratio with RT-200 (48)/M100: High Flow

Note: Tidal Volume Control and LCD indicator can be checked off from earlier Tidal Volume tests (See Section 2.0) Air/Oxygen Mixer Control and LCD indicator can be checked off from earlier Air/Oxygen Mixer tests (See Section 3.0).

7.8 MUTE/CANCEL

7.8.1 Muting An Alarm

7.8.1.1 Generate a Disconnect alarm.

7.8.1.2 Press the Mute/Cancel push-button control.

7.8.1.2.1 The audible alarm should mute for 30 seconds. After 30 seconds, the audible alarm should come back on.

7.8.1.2.2 The alarm LED should go from blinking to solid on for 30 seconds. After 30 seconds, the alarm LED should start blinking again.

7.8.1.2.3 The Alarm Message Center should still display the Disconnect alarm.

7.8.1.2.4 Fix disconnect condition. Alarm should deactivate.

7.8.2 Canceling an alarm

7.8.2.1 Disconnect external power. An External Power Fail alarm should occur.

7.8.2.2 Press the Mute/Cancel push-button control.

7.8.2.2.1 The audible alarm should stop.

7.8.2.2.2 The alarm LED should turn off.

7.8.2.2.3 The AMC should show no alarm.

7.9 MANUAL BREATH

7.9.1 Setup

7.9.1.1 Connect hose circuit to test lung.

7.9.1.2 Use the following settings

7.9.1.2.1 Mode = A/C.

7.9.1.2.2 Rate = 10 BPM.

7.9.1.2.3 I time = 1.0 sec.

7.9.1.2.4 Vt = 500 ml.

7.9.2 Press the Manual Breath push-button control during an expiratory pause.

7.9.2.1 The unit should give an audible beep.

7.9.2.2 A control breath at the given settings should be generated.

7.9.3 Press and release the Manual Breath push-button control during an inhalation or exhalation.

7.9.3.1 Nothing should happen.

7.9.4 Press and hold the Manual Breath push-button control during inhalation. When the current breath is over, and the test lung reaches baseline airway pressure.

7.9.4.1 The unit should give an audible beep

7.9.4.2 A control breath at the given settings should be generated.

Note: The Manual Breath push-button control should activate only one control breath when it is depressed, and it should only trigger at baseline airway pressure.

7.10 MODE

7.10.1 Off Mode

7.10.1.1 Turn Mode control switch to the OFF mode. Unit should turn off and be non-operational.

7.10.2 A/C Mode

7.10.2.1 Turn Mode control switch to A/C mode.

7.10.2.2 Unit should power up and go into A/C mode.

7.10.2.3 Verify the LCD screen reads "Mode = A/C".

7.10.3 SIMV Mode

7.10.3.1 Turn the Mode control switch to SIMV mode.

7.10.3.2 Unit should go into SIMV mode.

7.10.3.3 Verify the LCD screen reads "Mode = SIMV".

7.10.4 CPAP Mode

7.10.4.1 Turn the Mode control switch to CPAP mode.

7.10.4.2 Unit should go into CPAP mode.

7.10.4.3 Verify the LCD screen reads "Mode = CPAP".

7.10.4.4 In the CPAP mode, the Rate, Inspiration Time, and Tidal Volume controls are non-functional, and their corresponding LCD indicators should be blank.

7.10.5 CAL Mode

7.10.5.1 Turn the Mode control switch to CAL mode and turn it back to CPAP mode before the calibration is complete. The unit should give a Calibration Abort Alarm.

7.10.5.2 Turn unit to the CAL mode again.

7.10.5.2.1 Verify the unit calibrates.

7.10.5.2.2 The LCD reads "CAL = OK".

7.10.6 Autocal Valve Check

7.10.6.1 Turn Mode control switch to A/C mode.

7.10.6.2 Connect syringe to green transducer fitting using 1/8 ID tubing and pressurize to 20 cmH2O.

7.10.6.3 Turn Mode control to Cal mode and let unit calibrate.

7.10.6.4 Turn Mode control back to A/C mode.

7.10.6.5 Remove syringe from transducer fitting. The airway pressure baseline should be at 0 cmH2O.

8 LCD VISUAL INDICATORS:

8.1 Vmin

8.1.1 Turn unit to A/C mode.

8.1.1.1 The minute volume (Vmin) should be given in liters.

8.1.2 Turn unit to SIMV mode.

8.1.2.1 The Vmin display blanks in the SIMV, CPAP, and CAL modes.

8.2 INSPIRATION/EXHALATION

8.2.1 Indicator should display "INSPIRATION" during inspiration in A/C, SIMV, and CPAP modes.

8.2.2 Indicator should display "EXHALATION" during exhalation or expiratory pause in A/C, SIMV, and CPAP modes.

8.2.3 Indicator blanks in CAL mode.

8.3 POWER INFORMATION CENTER

Note: The Power Information Center (PIC) occupies a two line area in the LCD's lower left hand section. The first line is external power information. The second line is battery power information.

8.3.1 External Power Information (PIC Line 1) will display one of 5 different messages.

8.3.1.1 “EXT PWR ON” denotes operation from an external power source.

8.3.1.1.1 Connect external power source.

8.3.1.1.2 Verify PIC Line 1 reads “EXT PWR ON”

8.3.1.2 “EXT PWR LOW” occurs during operation with a low external power source.

8.3.1.3 “EXT PWR FAIL” occurs when external power fails during operation and a battery is connected.

8.3.1.4 “EXT CHK FUSE” occurs when external power fuse blows or is removed, and unit continues to operate on battery power.

Note: When the external power fuse is blow or removed, an External Power Fail alarm initially occurs. The PIC Line 1 displays the “EXT PWR FAIL” message. After pressing the Mute/Cancel push-button, the External Power Fail alarm is canceled, and the “EXT CHK FUSE” blinking message takes the place of the “EXT PWR FAIL” message.

8.3.1.5 PIC Line 1 is blank during normal battery operation.

8.3.2 Battery Power Information (PIC Line 2) will display one of 5 different messages.

8.3.2.1 External Power Connected. The second line will read

8.3.2.1.1 Battery icon "ON CHG" if the battery is being charged
8.3.2.1.2 Battery icon "CHK FUSE" if the battery fuse is blown or missing.
8.3.2.1.3 Blank if the battery is fully charged.
8.3.2.2 No External Power Connected. The second line will read
8.3.2.2.1 Battery icon "OK" if the battery is good.
8.3.2.2.2 Battery icon "LOW" if the battery is low.

8.4 Paw

Note: The Paw indicator represents a continuous and updating display of airway pressure. It displays the most recent 12-second period. Airway pressure amplitude along the vertical axis is also shown on adjacent bar graph. Each pixel is 2 cmH2O in the vertical axis. Markings along the horizontal axis represent 1-second intervals, and each pixel is 0.1 second in the horizontal axis.

8.4.1 Remove patient circuit from test lung
8.4.2 Occlude hose such that the airway pressure reaches 100 cmH2O.
8.4.2.1 Verify the Paw indicator goes to 100 cmH2O.
8.4.2.2 There should be no missing lines or pixels on zero baseline.

8.5 DIGITAL BAR GRAPH

Note: The digital bar graph corresponds with the Paw display. Each pixel is 2 cmH2O in the vertical axis. The markings on the bar graph are 10 cmH2O apart.

8.5.1 During the Paw test above.
8.5.1.1 Verify the digital bar graph goes to 100 cmH2O.
8.5.1.2 There should be no missing lines or pixels in the bar graph.

8.6 PEAK AIRWAY PRESSURE

8.6.1 Connect patient circuit to test lung.
8.6.2 Unit displays the peak airway pressure of the previous breath above the bar graph.
8.6.2.1 Verify display reads "PEAK=##cmH2O" where "##" is a one or two digit value representing the peak airway pressure in cmH2O.
8.6.2.2 Verify the value using test lung gauge.

8.7 MEAN AIRWAY PRESSURE

8.7.1 For Setup connect patient circuit to test lung.
8.7.2 Unit displays the mean airway pressure below the peak airway pressure display.
8.7.2.1 Verify display reads "MEAN=##cmH2O" where "##" is a one or two digit value representing the mean airway pressure in cmH2O.

9 LED INDICATORS:

9.1 CHARGE

9.1.1 For Setup connect external power supply and disconnect battery. Connect 30 ohm dummy load in place of battery.

9.1.2 Charge LED should come on. It may take a few minutes for charge LED to light.

9.2 ALARM

9.2.1 Generate a Disconnect alarm.

9.2.2 Alarm LED should blink.

9.2.3 Press the Mute/Cancel push-button. The Alarm LED should come on solid.

9.2.4 Fix disconnect condition, Alarm LED should turn off.

9.3 SYSTEM FAIL LED AND ALARM

9.3.1 For Setup connect external power and battery. Go into A/C mode.

9.3.2 Remove the top fuse.

9.3.2.1 An External Power Fail alarm should occur.

9.3.2.2 Press the Mute/Cancel push-button.

9.3.2.2.1 The External Power Fail alarm should cancel.

9.3.2.2.2 The PIC line 1 should read "CHK EXT FUSE".

9.3.3 Remove the bottom fuse with the top fuse still removed.

9.3.3.1 The System Failure LED should come on solid.

9.3.3.2 The audible alarm should give a continuous tone.

9.3.3.3 The LCD screen should blank.

9.3.3.4 The unit should shut down.

10 ALARMS

10.1 DISCONNECT

10.1.1 For Setup remove patient circuit from test lung.

10.1.2 A Disconnect Alarm should occur when the next breath is fired and no positive airway pressure rise is sensed.

10.1.3 Connect patient circuit to test lung. The Disconnect Alarm should cancel on the next breath.

10.2 10.2 FIO2 &O2 LOW/FAIL

10.2.1 For Setup set oxygen concentration to 60%. Connect patient circuit to test lung.

10.2.2 Lower oxygen tank pressure to 35 PSI +/- 2 PSI.

10.2.2.1 The O2 Low/Fail alarm should occur.

10.2.2.2 The FIO2 alarm should occur.
10.2.2.3 Verify the tidal volume is maintained by external air or compressor.
10.2.3 Turn oxygen concentration to 21%.
10.2.3.1 Alarms should cancel.
10.2.3.2 Verify the tidal volume is maintained by external air or compressor.
10.2.4 Set oxygen concentration back to 60%.
10.2.4.1 The O2 Low/Fail alarm should occur again.
10.2.4.2 The FIO2 alarm should occur again.
10.2.4.3 Verify the tidal volume is maintained by external air or compressor
10.2.5 Return oxygen tank pressure to 45 PSI +/- 2 PSI.
10.2.5.1 Alarms should cancel.
10.2.5.2 Verify tidal volume is maintained by oxygen with external air or compressor.

10.3 Vt & Vt SETTINGS

10.3.1 Setup
10.3.1.1 Use the following settings:
10.3.1.1.1 Rate = 15 BPM.
10.3.1.1.2 I time = 1.0 seconds.
10.3.1.1.3 Vt = 800 ml.
10.3.2 Change Vt to 1050 ml.
10.3.2.1 A Vt Settings alarm should occur.
10.3.2.2 Press the Mute/Cancel push-button.
10.3.2.2.1 The alarm LED and audible should turn off.
10.3.2.2.2 The AMC message should remain.
10.3.3 Increase Vt setting to 1150 ml.
10.3.3.1 A Vt alarm should occur
10.3.3.2 The alarm LED and audible should come back on.
10.3.3.3 The Vt alarm will displace the Vt Settings alarm as the first on the AMC, but Vt settings alarm will remain as the second alarm.
10.3.4 Decrease Vt setting to 500 ml.
10.3.4.1 Alarms should cancel.

10.4 I TIME TRUNCATED TO 3-SEC

10.4.1 Setup
10.4.1.1 Set I time control to fully counter clockwise. This is the default 1:2 I:E Ratio setting.
10.4.2 Turn the rate control to 6 BPM.
10.4.2.1 The I Time Truncated To 3-Sec alarm should occur.

10.4.2.2 Press the Mute/Cancel push-button.

10.4.2.2.1 The alarm LED and audible should turn off

10.4.2.2.2 The AMC message should remain.

10.4.3 Increase the rate to 7 BPM.

10.4.3.1 The alarm cancels and the AMC message blanks

10.5 EXTERNAL POWER FAIL: This alarm has been checked in section 6.2.2.1.

10.6 INVERSE I:E:

10.6.1 Setup

10.6.1.1 Use the following settings

10.6.1.1.1 Rate = 30 BPM.

10.6.1.1.2 I time = 1.0 seconds.

10.6.1.1.3 Vt = 800 ml.

10.6.2 Increase I time to 1.1 seconds.

10.6.2.1 An Inverse I:E alarm should occur.

10.6.2.1.1 Alarm is non mutable

10.6.2.1.2 Alarm is a Non-Operating alarm.

10.6.3 Decrease I time to 1.0 seconds

10.6.3.1 1 Alarm should cancel.

10.7 COMP

10.7.1 Setup

10.7.1.1 Use the following settings

10.7.1.1.1 Rate = 150 BPM.

10.7.1.1.2 I time = 0.2 seconds.

10.7.1.1.3 Vt = 200 ml.

10.7.1.1.4 External Air = “ON”.

10.7.2 Press the External Air push-button control.

10.7.2.1 The LCD indicator should read “OFF”.

10.7.2.2 The compressor should start to operate.

10.7.3 Press the External Air push-button control again after one compressor breath.

10.7.3.1 The LCD indicator should read “ON”.

10.7.3.2 The compressor should stop.

10.7.3.3 The external air valves should start operating.

Note: During this switching back and forth between External air and compressor operation, Vt and Disconnect alarms may be occurring. This is acceptable. The purpose of this procedure is to artificially induce a Comp alarm.

10.7.4 Press the External Air push-button control again after one external air breath.

10.7.4.1 The LCD indicator should read "OFF
10.7.4.2 The compressor should try to start.
10.7.4.3 Along with possible Vt and Disconnect alarms, a Comp alarm should occur
10.7.4.3.1 During Comp alarm, the external air valves supply the gas source.

Note: You can generate Failure Code 2 (No Gas, Comp) Alarm here by lowering external gases to below 35 PSI +/- 2 PSI.

10.8 TOTAL FLOW BACKUP

10.8.1 Setup
10.8.1.1 Use settings
10.8.1.1.1 Rate = 15 BPM.
10.8.1.1.2 I time = 1.0 sec.
10.8.1.1.3 Vt = 900 ml.
10.8.1.1.4 FIO2 = 21%.
10.8.1.1.5 External Air = "OFF".
10.8.2 Partially occlude the compressor inlet fitting such that the actual tidal volume is less than half of the set tidal volume. After 4-5 breaths..
10.8.2.1 A Total Flow Backup Alarm should occur.
10.8.2.2 Press the Mute/Cancel push-button.
10.8.2.2.1 The alarm LED and audible alarm should turn off.
10.8.2.2.2 The AMC message should remain.

Note: There are two alarms that cannot be checked during the final test procedures. They are Extended Non-Use and Preventative Maintenance. alarms.

11 SAFETY SHUTDOWN

Note: The Safety Shutdown (40 cmH2O for 4 seconds) is tested during the generating of Failure Code 5 alarm. See section 12.5.

12 VENT FAIL

Note: To do Ventilator Failure Code tests, a syringe and a piece of 1/8 ID tubing are needed.

12.1 VENTILATOR FAILURE CODE 1

Note: This Failure Code occurs when Self Check fails during startup. It cannot be checked during the final test procedures.

12.2 VENTILATOR FAILURE CODE 2

12.2.1 Setup
12.2.1.1 Use External Air.

12.2.1.2 Disconnect oxygen supply.
12.2.1.3 Generate a COMP alarm per Section 10.7.

12.2.2 After getting COMP alarm, disconnect external air and oxygen supplies.
12.2.2.1 Unit should shut down.
12.2.2.2 Verify unit gives a Failure Code 2 (No Gas, COMP) alarm.

12.3 VENTILATOR FAILURE CODE 3

Note: This Failure Code occurs when Excessive Airway Pressure is sensed during startup. It cannot be checked during the final test procedures.

12.4 VENTILATOR FAILURE CODE 4

Note: This Failure Code occurs when a memory check fails. It cannot be checked during the final test procedures.

12.5 VENTILATOR FAILURE CODES 5

Note: When testing Failure Code 5 the 40 cmH2O for 4 seconds Safety Shutdown will also occur.

12.5.1 Setup
12.5.1.1 Use settings
12.5.1.1.1 Mode = A/C.
12.5.1.1.2 Rate = 15 BPM.
12.5.1.1.3 I time = 1.0 sec.
12.5.1.1.4 Vt = 500 ml.
12.5.1.1.5 FIO2 = 21%.
12.5.1.2 Connect to test lung.
12.5.1.3 With unit operating, disconnect green transducer hose, and connect syringe with hose to transducer fitting. A disconnect alarm may occur, ignore it.

12.5.2 Slowly pressurize syringe until airway pressure is above 40 cmH2O. After 4 seconds above 40 cmH2O the safety shutdown should occur.
12.5.2.1 The system fail LED comes on.
12.5.2.2 Audible alarm comes on continuously.

12.5.3 Increase the airway pressure to +100 cmH2O. After 2 seconds
12.5.3.1 Unit should shut down.
12.5.3.2 Verify unit gives a Failure Code 5 (Exhaust Valve Failure) alarm.

12.6 VENTILATOR FAILURE CODE 6

12.6.1 Setup
12.6.1.1 Use Settings

12.6.1.1.1 Mode = A/C.
12.6.1.1.2 Rate = 15 BPM.
12.6.1.1.3 I time = 1.0 sec.
12.6.1.1.4 Vt = 500 ml.
12.6.1.1.5 FIO2 = 21%.

12.6.1.2 Connect to test lung. With unit operating, disconnect green transducer hose, and connect syringe with hose to transducer fitting. A disconnect alarm may occur, ignore it.

12.6.2 Decrease pressure with syringe until airway pressure is -10 cmH2O. After 1 1/2 seconds

12.6.2.1 The unit should shut down

12.6.2.2 Verify unit gives a Failure Code 6 (Excessive Negative Pressure) alarm.

12.7 VENTILATOR FAILURE CODE 7

Note: This Failure Code occurs when a Run-Time Transducer Calibration fails. It cannot be checked during the final test procedures.

13 USER PROGRAMS

Note: To go into the User Program mode, simultaneously press and hold the Mute/Cancel push-button and the Manual Trigger push-button. Turn on the unit. A menu appears along the top of the LCD. If the screen is so dark that it is not readable, then the unit must be upgraded per the CRO-04028. Press corresponding push-button switches to make selections.

13.1 BACKLIGHT THRESHOLD

13.1.1 Go into User Program Mode and go to Backlight Threshold menu.

13.1.2 Put finger about an inch away from backlight sensor and press the push-button over Save prompt. This will save the backlight threshold.

13.1.2.1 Pull finger away from the backlight sensor; the backlight should go out.

13.1.2.2 Fully cover the backlight sensor with finger; the backlight should go on.

13.1.3 Pull finger away from sensor and press push-button over Save prompt. This will save the backlight threshold.

13.2 CONTRAST THRESHOLD & TRIGGER LEVEL SENSITIVITY

13.2.1 Go into User Program Mode and go to Contrast Threshold menu.

13.2.2 Press the push-button above the Down prompt until the contrast gets faint. Press the Save prompt. When the unit goes into operational mode, the contrast should be faint.

13.2.3 Go to Trigger Level Sensitivity menu before exiting User Program Mode. In

the Trigger Level Sensitivity menu, press the Down prompt until the sensitivity level is 1.0 cmH2O.

13.2.4 Exit the User Program mode by pressing the Exit push-button. Do not turn off unit. Once in normal operating mode:

13.2.4.1 the contrast should be faint.

13.2.4.2 Use settings:

13.2.4.2.1 Mode = A/C.

13.2.4.2.2 Rate = 6 BPM.

13.2.4.2.3 I time = 1.0 sec.

13.2.4.2.4 Vt = 500 ml.

13.2.4.2.5 FIO2 = 21%.

13.2.4.3 Use test lung.

13.2.4.3.1 Pull up gently on test lung to simulate a patient's spontaneous breath. Verify the unit triggers an assisted breath every time the negative 1.0 cmH2O Trigger Level is reached.

13.2.5 Turn off unit. Go back into User Program Mode and go to Contrast Threshold menu.

13.2.6 At Contrast menu, press the Up prompt until the contrast is good; press the Save prompt. When a unit goes into operational mode, the contrast should be good.

13.2.7 Go to Trigger Level Sensitivity menu before exiting User Program Mode. In the Trigger Level Sensitivity menu, press the Up prompt and increase the Trigger Level to 5.0 cmH2O.

13.2.8 Exit the User Program mode by pressing the Exit push-button. Do not turn off unit. Once in normal operating mode:

13.2.8.1 The contrast should be good.

13.2.8.2 Use settings from 13.2.4.2

13.2.8.3 Use test lung.

13.2.8.3.1 Pull up on the test lung to simulate a patient's spontaneous breath. It should be more difficult to generate an assisted breath than when the Trigger Level was lower. Verify unit generates an assisted breath every time the negative 5.0 cmH2O Trigger Level is reached. Turning unit off resets Trigger Level Sensitivity back to its default value of 2.0 cmH2O.

13.3 SPONTANEOUS FLOW

13.3.1 Go into User Program Mode and go to Spontaneous Flow menu.

13.3.2 Press the Down prompt until the Spontaneous Flow reads 10 LPM. Exit the User Program mode. Do not turn off unit.

13.3.3 Go into SIMV mode.
13.3.3.1 Connect hose circuit to RT-200 (36)/M100: High Flow: Gas Type: Air.
13.3.3.2 Use 21% external air.
13.3.3.3 Disconnect green transducer line from patient valve. Cover up fitting hole and generate a negative pressure by gently pulling in on green transducer hose using a syringe. Either a demand breath or an assisted breath will be generated. The flow of the demand breath should be 10 LPM (+/- 10%).
13.3.4 Turning unit off resets Spontaneous Flow back to its default value of 60 LPM.

13.4 DEMO MODE

13.4.1 Go into User Program Mode and go to Demo Mode menu.
13.4.2 Press the Set prompt, and exit the User Program mode. Do not turn off unit.
13.4.3 The unit is in Demo mode.
13.4.3.1 The mode should read "MODE=A/C DEMO.
13.4.3.2 Connect disposable patient circuit to test lung.
13.4.3.2.1 The exhaust valve and test lung should not inflate.
13.4.3.2.2 All the gas should flow out the exhaust port of patient valve.
13.4.3.2.3 A false airway pressure waveform should be generated in the Paw and bar graph LCD displays.
13.4.3.3 Disconnect patient circuit from test lung.
13.4.3.3.1 No Disconnect alarm should sound.
13.4.3.3.2 The false airway pressure waveforms should continue.

14 BACKUP VENT

14.1 SETUP

14.1.1 Use External Air.

14.2 In User Program mode go into Backup Vent menu. Press Test prompt.

14.2.1 Verify the unit goes immediately into testing Backup Vent and the following happens
14.2.1.1 LCD screen should blank
14.2.1.2 Alarm LED blinks
14.2.1.3 System Failure LED comes on solid
14.2.1.4 Audible alarm gives a repeating 4 to 5 pulse alarm.
14.2.2 Rate in Backup Ventilator
14.2.2.1 Connect hose circuit to RT-200 (45)/M100: High Flow.
14.2.2.2 Rate should be 12 BPM +/- 10%.
14.2.3 I time in Backup Ventilator
14.2.3.1 Connect hose circuit to RT-200 (46)/M100: High Flow.

14.2.3.2 I time should be 1.60 Sec +/- 10%.

14.2.4 Flow in Backup Ventilator

14.2.4.1 Connect hose circuit to RT-200 (36)/M100: High Flow: Gas Type: Air.

14.2.4.2 Flow should be 30 LPM or greater.

14.2.5 Pip Relief in Backup Ventilator

14.2.5.1 Connect hose circuit to test lung. Set compliance to .015 L/cmH2O. Resistance = 5.

14.2.5.2 Using test lung pressure gauge, verify that Pip relief occurs at 40 cmH2O +/- 10%.

14.2.6 Manual Trigger in Backup Ventilator

14.2.6.1 Connect hose circuit to test lung. Set compliance to .015 L/cmH2O.

14.2.6.2 Press the Manual Trigger push-button.

14.2.6.2.1 Verify that gas flows as long as the push-button is held.

14.2.6.2.2 When the airway pressure reaches 40 cmH2O, the gas flow should stop.

15 POWER:

15.1 BATTERY

15.1.1 Measure battery voltage (Load). Value should be within range of 11.8V - 14.5V.

15.1.2 Low Battery Alarm

15.1.2.1 Setup. Disconnect external power and battery. Connect unit's battery connector cable to variable power source. Put voltage to 12 VDC and turn on unit.

15.1.2.2 Lower voltage until Low Battery Alarm occurs. This should occur within the voltage range of 11.1V - 11.7V.

15.1.2.2.1 AMC should show BATTERY LOW/FAIL alarm.

15.1.2.2.2 PIC Line 2 should show Battery Icon "LOW"

15.1.3 Battery Fail

15.1.3.1 Setup is the same setup as 15.1.2.1.

15.1.3.2 Lower voltage until system shutdown occurs. This should occur within the voltage range of 8.5V - 9.3V.

15.1.3.2.1 Unit should shut down

15.1.3.2.2 System failure LED should come on continuously.

15.1.3.2.3 Audible alarm should come on continuously.

15.1.4 Charger Voltage

15.1.4.1 Disconnect battery connector cable from power source. Connect variable power source to unit's external power jack. Set voltage to 12 VDC.

15.1.4.2 Measure voltage at unit's battery connector cable. Value should be within range of 13.2V – 14.5V.

15.2 EXTERNAL POWER

15.2.1 External Power Low

15.2.1.1 Disconnect battery connector cable from power source. Connect variable power source to unit's external power jack. Set voltage to 12 VDC and turn on unit.

15.2.1.2 Lower voltage until External Power Low alarm occurs. This should occur within voltage range of 10.5V - 11.1V.

15.2.1.2.1 AMC should show EXTERNAL POWER LOW alarm.

15.2.1.2.2 PIC Line 1 should show "EXT PWR LOW"

15.2.1.3 Lower voltage until system shutdown occurs. This should occur within the voltage range of 9.00V - 10.50V.

15.2.1.3.1 Unit should shut down

15.2.1.3.2 System failure LED should come on

15.2.1.3.3 Audible alarm should come on continuously.

16 EEPROM:

Note: Protection enabling is done during initial computer calibration. Verify this has been done by finding the text file with a corresponding serial number of unit.

16.1 REAL TIME CLOCK RESET

16.1.1 Setup

16.1.1.1 Connect RS232 to external power supply.

16.1.1.2 Connect external power supply to unit. Turn on unit.

16.1.1.3 Connect RT-200/M100 to computer. Turn on RT-200/M100 and computer.

16.1.1.4 Go into computer calibration program.

16.1.2 To Reset Real Time Clock

16.1.2.1 Select the "calibration" menu.

16.1.2.2 Select "Reset RTC". Note: A reading of 0 or 44 days and 0 hours should be expected.

17 COSMETICS

17.1 Connector Panel Side

17.1.1 Verify Exhalation valve hosebarb and Transducer hosebarb are tight.

17.1.2 Verify nuts to Oxygen and External air fittings are tight.

17.1.3 Verify Outlet Fitting is flush with connector panel and tight.

17.1.4 Cover and external power jack are properly positioned.

17.2 Handle Side

17.2.1 Verify handle is tight.
17.2.2 Verify caution label is properly positioned.
17.2.3 Verify exhaust port nut is tight.
17.2.4 Verify three screws holding 22mm inlet port are tight.

17.3 Back Side

17.3.1 Verify three screws mounting compressor are in properly.
17.3.2 Condensed Operation Instructions should be mounted on back.
17.3.3 Four round bumper feet should be on back of case.

17.4 Front Side

17.4.1 Verify each knob is aligned properly, is tight, and has its respective cap.
17.4.2 Press each white pushbutton to verify operation.
17.4.3 Verify black switch guard around manual trigger button is tight.
17.4.4 Verify backlight sensor is properly in its window.
17.4.5 Verify three LEDs are properly in their windows.

17.5 Battery Compartment Side

17.5.1 Verify Filter PCB is soldered correctly to the Lemo connector.
17.5.2 Input power inductor is RTV'd.

17.6 Bottom Side

17.6.1 Verify four bumper feet are on the bottom of the unit.

17.7 Shake Test/Cleaning

17.7.1 Shake unit and listen for any loose parts (Test Dept. Function).
17.7.2 Clean case, front door and LCD screen (Production Dept. Function).

18 ACCESSORIES:

18.1 Check work order to determine required accessories.

18.1.1 Check off Required boxes

18.2 Gather required accessories and check off Supplied boxes.

18.3 EXTERNAL POWER SUPPLY

18.3.1 Verify external power supply's serial number.
18.3.2 Clean using a soft cloth or paper towel with Staticide.
18.3.3 Coil and rubber band the wires.

19 TEST EQUIPMENT

19.1 Record serial numbers of all test equipment used during test.